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## Utility of the Beck Depression Inventory to Screen for and Track Depression in Injection Drug Users Seeking Hepatitis C Treatment

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### Abstract

**Objective**—Treating acute HCV in injection drug users (IDUs) is complicated by a high prevalence of psychiatric comorbidities that may lead to increased risk for depressive complications of interferon treatment. Effective screening strategies are needed to help non-psychiatric clinicians identify depressive disorders.

**Methods**—Thirty IDUs with acute HCV completed the Beck Depression Inventory (BDI), underwent a psychiatric examination, and were randomized to 24 weeks of pegylated interferon treatment (IFA) or observation (OBS). Sensitivity, specificity, positive (PPV) and negative predictive values (NPV) of the BDI for diagnosing depression (with a cutoff >10) were calculated. The psychiatrist's diagnosis was used as the gold standard. Depression severity was assessed over time with the BDI.

**Results**—Forty-seven percent of individuals met criteria for a depressive disorder. Sensitivity (91%) and NPV (92%) were high for the BDI; specificity (58%) and PPV (56%) were low. BDI worsened in 2 patients completing the study (one IFA, one OBS); two IFA patients were discontinued for possible depression-related complications. At baseline, subject-rated fatigue was associated with alanine aminotransferase (ALT) level.

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This study was approved by the Institutional Review Boards of all participating centers. Informed consent was obtained from all study participants.

**Conclusion**—The BDI is an adequate tool for ruling out depressive disorders in active IDUs with acute HCV, but specificity is low. Psychiatric consultation is recommended for all active IDUs being considered for acute HCV treatment.

### Keywords

Depression; Screening; Injection Drug Use; Acute Hepatitis C; Interferon-alpha

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## INTRODUCTION

An estimated 19,000 new hepatitis C (HCV) infections occur yearly in the United States [1], with up to 60 percent involving injection drug users (IDUs) [2,3]. Increasing evidence supports early treatment of HCV infection with interferon-based regimens because of superior response rates in acute compared to chronic infection [4-6]. However, most providers do not treat acute HCV in active IDUs [7]. Additionally, in clinical trials excluding IDUs, approximately 10% of individuals treated with interferon-based therapy develop depression necessitating discontinuation of therapy [8,9]. Given that active injection drug use (IDU) is associated with increased rates of depression and other psychiatric symptoms compared to the general population [10], this likely represents another barrier to treating HCV in IDUs.

In individuals presenting to Hepatology clinics, most of whom are not active drug users, concern about the risk of interferon-induced depression has prompted evaluation of strategies to minimize depressive consequences of interferon-based therapies. Prophylactic use of antidepressant medications in all patients may not be practical or beneficial [11], though one clinical trial demonstrated reduced rates of depression in interferon-treated malignant melanoma patients pretreated with paroxetine [12]. Therefore, the use of depression screening tools prior to initiating treatment may help identify which patients warrant prophylactic antidepressant treatment. However, screening for depression in this population can be challenging, as even non-depressed individuals commonly endorse symptoms, such as fatigue and disturbed sleep, that would register on depressive inventories. Depression screening in an active IDU population may be even more problematic since “depressive” symptoms may actually reflect the physical effects of ongoing substance abuse or withdrawal, personality disorders associated with impulsive behavior and drug abuse, or adverse psychosocial circumstances resulting from drug abuse, such as homelessness [10,13,14]. For these reasons, common depression screening tools need additional validation in an active IDU population.

The Beck Depression Inventory [15] is a patient-rated scale and screening instrument for depression that focuses primarily on the cognitive symptoms of depression and less on somatic symptoms. For these reasons, the BDI is frequently used in clinical practice and in studies focused on depression in medical illness, including HCV [16]. The BDI has previously shown modest to good validity in screening for depression in non-IDU HCV patients [17,18] and following symptom change over time in chronic HCV patients receiving interferon/ribavirin treatment [18]. However, data on the utility of the BDI in screening for depression in active drug users with hepatitis C are lacking.

We examined the utility of the BDI as a depression screening instrument using a semi-structured diagnostic interview performed by a psychiatrist to confirm the presence or absence of depressive disorder in a trial investigating the safety and efficacy of pegylated interferon treatment of acute HCV in active IDU patients. Additionally, we evaluated the utility of BDI-defined cutoffs for determining when to pre-treat patients receiving interferon therapy for acute HCV.

## METHODS

### Subjects

This study was conducted in collaboration with an urban county public health research group conducting screening for hepatitis C antibody every 6 months among active IDUs. Acute hepatitis C infection was defined as either documented seroconversion within one year of a negative hepatitis C antibody test or a newly positive hepatitis C antibody in conjunction with a clinical syndrome compatible with acute hepatitis C, negative tests for other etiologies of elevated liver enzymes, and liver enzymes elevated >10 times the upper limit of normal. Active IDUs with acute HCV were recruited between September 2003 and December 2005 [19,20] and evaluated for a randomized trial of 24 weeks of pegylated interferon [4] versus 24 weeks of observation only (the results of this clinical trial are being analyzed and will be presented in a separate communication). All participants completed the self-rated Beck Depression Inventory (BDI) at screening [15]. In addition, patients received a semi-structured diagnostic interview by a board-eligible or board-certified psychiatrist (CP, JV, PH, or PS). This interview was closely modeled on the MINI Psychiatric Diagnostic Interview [21] and contained the following modules: psychotic disorders, mood disorders, anxiety disorders, substance use disorders, anorexia nervosa and bulimia, antisocial personality disorder and borderline personality disorder. Psychiatrists were not blinded to the BDI score at the time of interview.

Eligibility criteria for the study included: age  $\leq 15$  years; acute HCV infection as defined above; no comorbid unstable, severe psychiatric illness that was felt to require separate psychiatric management or impair the patient's ability to comply with study procedures; otherwise healthy with no significant chronic or unstable medical conditions (including anemia, rheumatologic disease, other chronic infection, thyroid disease, gout); for women of childbearing age, the patient could not be pregnant or nursing; adequate English comprehension to allow completion of self-rated scales; willingness and ability to give written informed consent.

Participation was further influenced by the screening Beck Depression Inventory (BDI) score. For the purposes of this study, a BDI score > 30 was considered to indicate "severe depression", a score of 21-30 indicated "moderate depression", a score of 11-20 was indicated "mild depression" and a score < 11 indicated no depression. If a potential patient's BDI score was > 30 (severe depression) at baseline, a study psychiatrist started an antidepressant medication (unless otherwise contraindicated); if the patient was already taking an antidepressant medication, a dose increase or switch to another medication was considered. The patient was then re-evaluated eight weeks later: if the BDI score improved to < 21 (mild to no depression), and the psychiatrist concurred that depression had improved, the individual was then eligible for randomization. Participants with mild to moderate depression (BDI score 11-30) were started on an antidepressant medication; if the patient was already taking an antidepressant medication, a dose increase or switch to another medication was considered. These patients were considered immediately eligible for randomization. Many patients were either currently taking or had previously taken antidepressant medications. This information was taken into account when selecting antidepressant medication. Participants with no depression (BDI scores < 11) were randomized without starting an antidepressant medication (but were allowed to continue on current antidepressant medications, if any).

### Procedures

Eligible patients were randomized to 24 weeks of pegylated interferon therapy (IFA) or observation only (OBS). IFA-randomized individuals were seen weekly until week 24, and then monthly until week 48; these patients completed the BDI weekly for the first 24 weeks, then again at weeks 28 and 48. OBS-randomized individuals were seen monthly for 24 weeks, completed a follow-up BDI at the 24 week visit, and were then offered 48 weeks of pegylated

interferon and ribavirin at the end of the 24-week controlled study period. All study procedures were approved by the University of Washington institutional review board, and every participant gave written informed consent prior to participating.

### Data analyses

The sensitivity, specificity, positive predictive value and negative predictive value of the BDI for diagnosing any significant depressive disorder (major depressive disorder, bipolar disorder currently depressed, dysthymia, or depressive disorder not otherwise specified) were calculated using the psychiatrist confirmed diagnoses as the gold-standard. In patients completing the 24 week study, baseline and 24 week BDI scores were compared to assess effects of interferon and pre-treatment with antidepressant medications based on a priori defined BDI cutoffs. T-tests were used to compare means on continuous variables, with an *a priori* alpha level of 0.05.

## RESULTS

Thirty-two IDUs with acute HCV completed the BDI at initial screening and 30 underwent a structured psychiatric examination (2 patients did not return for further assessment). Eighteen patients had genotype 1 HCV, 2 had genotype 2 HCV, and 10 had genotype 3 HCV. Table 1 gives the demographics and psychiatric diagnoses at baseline for the 30 patients that completed both the screening BDI and psychiatric evaluation.

Depressive disorder was present in 11 of 30 patients (37%); five additional patients (17%) had a history of depressive disorder, but no active disease, giving a total of 16 patients (53%) with a current or past history of depressive disorder. Twelve patients (40%) had at least one currently active anxiety disorder. Twenty-one patients (70%) had at least one currently active Axis I diagnosis, and seven patients (23%) had at least two active Axis I diagnoses. Five of 30 patients (17%) had a diagnosis of antisocial or borderline personality disorder. Only five of 30 patients (17%) had no active Axis I or II diagnosis and no history of depressive disorder. All patients reported a current or past history of at least two substance use disorders including recent active injection drug use ranging from daily (53%) to one or more times per month (43%), with one patient reporting use less than one time per month.

The diagnostic accuracy of the BDI for depressive disorders is shown in Table 2. Using a traditional cutoff of > 10 to diagnose at least mild depression, the BDI had a sensitivity of 91%, specificity of 58%, positive predictive value of 56%, and negative predictive value of 92%. Only one subject was diagnosed with a depressive disorder (dysthymia; BDI=10) and did not have a baseline BDI score > 10; however, eight patients had a BDI score > 10 but were not found to have a currently active depressive disorder. Based on *a priori* BDI cutoffs, 12 patients (40%) had no depression (BDI < 11), 7 patients (23%) had mild depression (BDI 11-20), 7 patients (23%) had moderate depression and 4 patients (13%) had severe depression. A receiver operative characteristic (ROC) curve demonstrated that a cutoff of 11/12 for diagnosing depression performed slightly better with a sensitivity of 91%, specificity of 63%, positive predictive value of 59%, and negative predictive value of 92%.

To assess whether non-depressive psychiatric disorders explained the poor specificity of the BDI, analyses were performed in patients not diagnosed with a depressive disorder. Among these patients, having any psychiatric diagnosis was associated with a somewhat higher BDI score (16.3 vs. 8.4,  $p=0.15$ ). We hypothesized that patients with anxiety and/or personality disorders would have higher BDI scores even when not depressed compared to patients without these conditions: this difference approached statistical significance (18.9 vs. 8.6,  $p=0.06$ ). Of note, the mean BDI score was quite low (5.3) in the 3 patients diagnosed with a psychotic but no depressive disorder, and was even lower than the mean BDI score in patients without any psychiatric diagnosis (8.4).

To assess whether symptoms associated with acute HCV might explain the poor specificity of the BDI, viral load and alanine aminotransferase (ALT) were assessed in relation to somatic symptoms rated by the BDI (e.g., sleep disturbance, fatigue). Patients responding 1 (“I get tired or fatigued more easily than usual”) or 2 (“I am too tired or fatigued to do a lot of the things I used to do”) on the BDI fatigue item had a higher ALT than those who responded 0 (334 vs. 94,  $p=0.002$ ). Among patients not diagnosed with depression, ALT was also significantly higher in patients reporting fatigue (338 vs. 91,  $p=0.028$ ). ALT level was not associated with other BDI items, and viral load was not associated with any BDI item.

Seven of 30 individuals completing the screening BDI and psychiatric evaluation were excluded from the randomized trial or were lost to follow-up before enrollment. Of the remaining 23 patients, 9 received 6 months interferon treatment (IFA), and 14 were assigned to the observation arm (OBS). Five of the 23 randomized patients did not complete the 24-week study period, including two on active treatment and three in the control arm. One IFA participant was discontinued from treatment at week 11 when he presented to the emergency department (ED) complaining of active suicidal ideation. This individual had a baseline BDI score of 30 and was on an antidepressant medication at the time of his presentation to the ED. Another IFA participant fatally overdosed on heroin and alcohol during the first week of interferon therapy. His baseline BDI score was 9, and his BDI score 2 days before overdose was 10. This individual had been hospitalized twice previously for similar overdoses, and no suicidal ideation had been reported to friends or providers prior to the overdose. This event was determined by the study Data and Safety Monitoring Board to be an accidental overdose. Following 24 weeks of observation for the 14 OBS participants, two cleared the viral infection, three received interferon treatment, one developed a substance-induced psychosis and was considered not appropriate for treatment, one was incarcerated, and seven were lost to follow-up.

Of the 18 individuals who completed the 24 week study (7 IFA, 11 OBS), 11 had a baseline BDI score  $> 10$  (4 IFA, 7 OBS) and 10 were treated with antidepressant medications. One patient (randomized to the OBS arm) had a baseline BDI of 22 but was not diagnosed with a depressive disorder by the study psychiatrist. Because of ongoing alcohol abuse, opiate abuse, and high impulsivity, the psychiatrist recommended against starting an antidepressant medication. An additional four patients had a baseline BDI score  $< 11$  but were either taking antidepressant medications upon entry into the study or were started on antidepressant medications during the study. For the 14 patients treated with antidepressant medications during the study, medications varied and included fluoxetine, paroxetine, venlafaxine, bupropion and mirtazapine at standard therapeutic doses.

Change in BDI score over time for both study arms is shown in Figure 1. By the 24 week endpoint, the BDI score improved in all 11 patients with a baseline BDI score  $> 10$ , with 6 achieving BDI-defined remission of depressive symptoms ( $BDI \leq 10$ ). Two individuals with  $BDI \leq 10$  at baseline showed a  $BDI > 10$  at the 24 week endpoint, including one IFA and one OBS patient.

## DISCUSSION

The prompt treatment of acute HCV may lead to improved HCV clearance compared to treatment of chronic HCV [4-6], but is rarely recommended for patients who continue to use injection drugs (IDUs). This is primarily due to concerns about poor adherence to treatment and high risk of re-infection. An additional concern is that IDUs have a high prevalence of concomitant psychiatric illness (especially depressive disorders) that may put them at higher risk for depressive complications of interferon-based treatment regimens. However, because of the clinical benefits of treating acute HCV, some clinicians may consider initiating



interferon-based treatment in active IDU with acute HCV. An easy-to-use clinical tool to guide decisions about antidepressant therapy would be valuable to these non-psychiatric clinicians.

This study was conducted in a sample of young, urban patients with active IDU and acute HCV, and represents the first report on treatment of acute HCV in this population. Although this decreases the ability to generalize these results to other HCV populations, it also represents one of the few studies focused on this important group. Importantly, these data highlight the high comorbidity of psychiatric illness in this population, with greater than 80% of patients diagnosed with at least one significant current or past psychiatric diagnosis. Depressive disorders were the most common diagnoses, with more than half (53%) of patients having an active depressive diagnosis or history of depression. Of note, 40% of patients had at least one active anxiety disorder, but only 17% of patients had a clinically significant personality disorder.

As a screening instrument using traditional cutoffs for defining at least mild depression, the BDI showed excellent sensitivity and negative predictive value, with only one subject being misclassified as not depressed; this subject was diagnosed with dysthymia, a disorder defined by relatively few but chronic depressive symptoms. This suggests that the BDI is an excellent tool for ruling out depressive disorders in acute HCV IDUs seeking treatment, confirming prior reports in other HCV populations [17,18]. Despite its high sensitivity, the BDI showed poor specificity and positive predictive value. Using the slightly higher cutoff determined by the ROC curve did not substantially improve the predictive utility of this instrument. Therefore, the BDI must be viewed more cautiously as an instrument to diagnose depressive disorders in this population and determining treatment at baseline. Based on these data, nearly half of the patients diagnosed with depression using a BDI > 10 cutoff would not have an actual depressive disorder on psychiatric examination and may not require antidepressant treatment. This suggests that psychiatric consultation for patients with an elevated BDI score is necessary to clarify diagnosis and determine appropriate treatment recommendations.

This poor specificity of the BDI is probably due in part to the high frequency of non-depressive psychiatric disease in this population, where symptoms related to other psychiatric illnesses are being captured on the BDI. Mean BDI score (among non-depressive disorder patients) was higher in patients with any other psychiatric disorder, and approached being statistically significantly higher among patients with any anxiety and/or personality disorder. Interestingly, our results suggest that a psychotic disorder (in the absence of depression) may not contribute to an elevated BDI score. Since ALT was associated with BDI-rated fatigue in this study, it is also possible that symptoms secondary to acute HCV may have contributed to higher BDI scores in some non-depressed patients.

In this study, BDI cutoffs were used to determine whether patients needed treatment for depression prior to interferon treatment. Using this strategy, depression severity increased in only 2 patients (1 randomized to active treatment, 1 randomized to observation) among those that completed therapy. Neither of these patients was diagnosed with depression at baseline by either the BDI or the psychiatric exam, and one participant was able to complete the treatment arm despite worsening depressive symptoms.

Two of 9 patients receiving interferon treatment had complications potentially related to increased depression: one developed increased suicidal ideation, and one fatally overdosed. Although the fatal overdose was deemed to be accidental by the DSMB for the study, an increase in depressive symptoms cannot be ruled out.

Limitations of this study include the small sample size and 40% dropout over the treatment course. Additionally, the study psychiatrists were not blinded to baseline BDI score at time of interview, potentially affecting their diagnostic assessment and inflating the sensitivity of the

scale. As patients were managed clinically, antidepressant treatments were not standardized, but instead based on best clinical judgment of the study psychiatrist – this led to a broad range of medications used in the study such that specific efficacy or safety of one versus another cannot be determined. It is also possible that antidepressant medications were over-utilized in this study, as the BDI scores were used to determine initiation of antidepressant medication. Finally, because the BDI score was used to determine the need for antidepressant medications, the utility of the psychiatric exam in making these decisions could not be explored.

Based on these data, the BDI demonstrated an excellent negative predictive value in this rarely-studied population, indicating that it is a reasonable screening tool to rule-out clinically significant depressive disorders in active IDUs with acute HCV. It can also be used to guide decisions about initiating or adjusting anti-depressant medication during IFA-based treatment. The poor specificity of the BDI in this population is likely due to the high prevalence of other psychiatric diseases and constitutional symptoms associated with HCV infection. Given the high psychiatric comorbidity in this patients enrolled in this study (and the poor specificity of the BDI), psychiatric consultation is recommended for all such patients being considered treatment of acute HCV.

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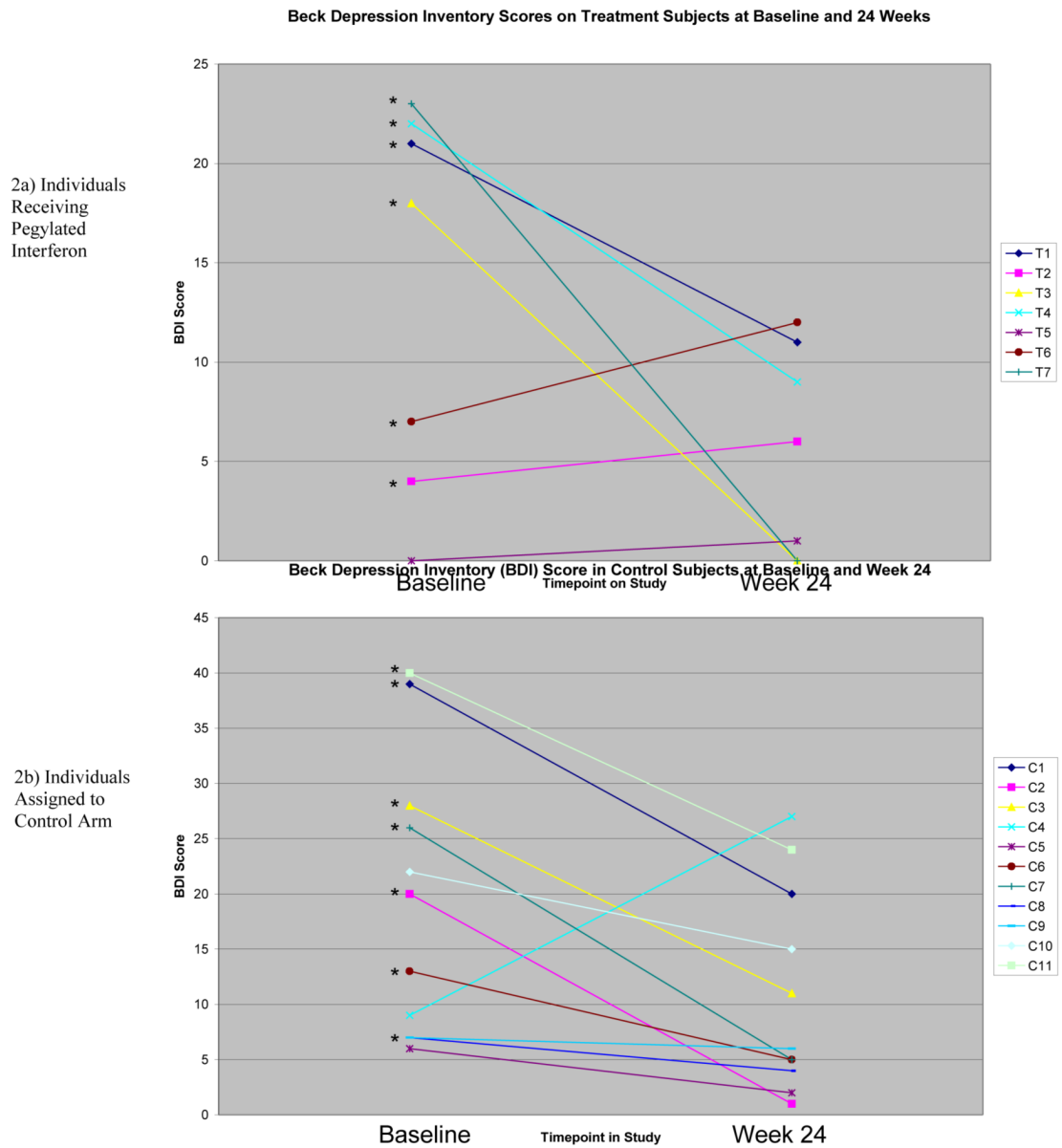
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**Figure 1.** Change in Beck Depression Inventory (BDI) Score from Baseline to Week 24 in Treatment (top) and Control (bottom) groups. Asterisks show participants taking antidepressant at any time during the study, including patients on antidepressant medications upon entering the study, started on medications at baseline or started on medications during the study. For one subject in the control arm (C10) with a BDI > 10, the study psychiatrist did not feel it was appropriate to start an antidepressant medication per the algorithm. Please see text for details.

**Table 1**

Patient demographics and psychiatric diagnoses at baseline (N=30)

	Mean (SD) or N (%)
Age	28.0 (6.6)
Male	23 (77%)
Caucasian	26 (87%)
Years of education	12.1 (2.1)
Currently homeless	16 (53%)
Current or past legal history	22 (73%)
Current or past violence history	11 (37%)
History of physical or sexual abuse	13 (43%)
Frequency of current drug use:	
Daily	16 (53%)
Less than daily	14 (47%)
Psychiatric medication use:	
Never	9 (30%)
Past	13 (43%)
Current	8 (27%)
Past suicide attempt	11 (37%)
Psychiatric diagnosis <sup>†</sup> :	
None	5 (17%)
Major Depressive Disorder	4 (13%)
Bipolar Disorder, depressed	0 (0%)
Dysthymia	2 (7%)
Depression Not Otherwise Specified	5 (17%)
Any active depressive disorder	11 (37%)
History of depressive disorder (not currently active)	5 (17%)
Generalized Anxiety Disorder	5 (17%)
Post-Traumatic Stress Disorder	4 (13%)
Obsessive Compulsive Disorder	2 (7%)
Panic Disorder	1 (3%)
Other anxiety disorder	4 (13%)
Any anxiety disorder <sup>‡</sup>	12 (40%)
Psychotic disorder	3 (10%)
ADHD	2 (7%)
Antisocial personality disorder	3 (10%)

	Mean (SD) or N (%)
<b>Borderline personality disorder</b>	2 (7%)

<sup>†</sup>Patients could have more than one psychiatric diagnosis

<sup>‡</sup>Some patients had more than one anxiety disorder

**Table 2**

Diagnostic accuracy of the BDI for depressive disorders in active injection drug users with acute HCV

	Depressive disorder		Total
	Present	Absent	
BDI > 10	10	8	18
BDI ≤ 10	1	11	12
Total	11	19	30

Sensitivity =  $10/11 = 91\%$ ; Specificity =  $11/19 = 58\%$ ; Positive Predictive Value =  $10/18 = 56\%$ ; Negative Predictive Value =  $11/12 = 92\%$